

of Southern California, and further held the claims unpatentable based on the Examiner's touted uses of the combination in everyday practice.

To begin, the affidavit enclosed and referenced above, is believed to overcome both the Examiner's 102 (a) or (f) rejections as well as the 103(a) rejection. As stated in the Affidavit, the study originally conducted by the University of Southern California was published November 18, 1989, and only addressed the use of aspirin within the residents of the retirement community. Given this, it should be noted that the study was published more than eight months after the filing date of the inventor's original patent application. Furthermore, the published study did not address the combination of aspirin and vitamins, it only addressed the use of aspirin. In conducting the study there was data that was incidentally gathered, some of which also referred to the use of vitamins, however, the data collected was not compiled or appreciated until the inventor of the present invention inquired into whether there was information regarding vitamin use and further requested the compilation and analysis of any data collected that pertained to the use of aspirin and vitamins in combination.

Therefore, the affidavit demonstrates that a rejection under §102 (f) would be in error because the invention was invented by the Applicant and not by another. The data collected for the study conducted to study the effects of aspirin use by the University of Southern California included the collection of other data, not intended for use or appreciated by the researchers. It was only through the inquiry and subsequent request of the Applicant, who had already conceived of the invention and filed an application, that the data collected was compiled and sent to the Applicant for analysis. As held by the Federal Court in *Ralph W. McKee and Harold Perpall v. Granton & Knight Co.*, "Prior accidental production of the same thing, where character and function are not recognized, does not anticipate." See 87 F.2d 262 (4th Cir. 1937). Furthermore, not only did the study conducted by the University of Southern California solely address the use of aspirin, it was conducted and published more than eight months after the filing date of the original application by the Applicant, again demonstrating that the Applicant is the inventor of the present invention. The Applicant respectfully requests the Examiner remove the rejection based on §102(f).

Applicant continues to refer to the affidavit in overcoming the §102(a) rejection. To begin it is stated that the above-referenced study conducted by the University of Southern California that addressed the effects of aspirin use was published November 18, 1989, however it is necessarily noted that the later compiled data and analysis carried out regarding the combination of aspirin and niacin, as was requested by the Applicant, was not published. This information was inquired into by the Applicant and then compiled by the University for the Applicant's own research and subsequent patent application. The information pertaining to the combination was not published or made public, the information was also not used by the University prior to the invention of the Applicant. Therefore the Applicant respectfully requests that the Examiner remove the rejection based on §102(a).

Finally, the Applicant again refers to the above-referenced affidavit in order to overcome the §103(a) obviousness rejection. Again the Examiner has rejected the patent application based on the study conducted by the University of Southern California. In order to establish obviousness there must be three base criteria: a) there must be some suggestion or motivation in the references to modify the teachings, b) there must be a reasonable chance of success, c) the prior art references must teach all of the claim limitations. As established by the affidavit, there isn't a prior art reference cited that teaches the claim limitations of the present invention. The study cited by the Examiner is not prior art over the present invention in that it does not teach the scope of the invention, was not published, and was in fact invented by the Applicant of the present application. It was the Applicant that first made the suggestion to analyze the other data collected and it was the Applicant that presumed a reasonable chance of success of obtaining the same results as set forth in the Applicant's patent application. Therefore, it is again respectfully requested that the §103(a) rejection be withdrawn on the basis of the invention being obvious in light of the study conducted by the University of Southern California.

The Examiner further based the §103(a) rejection on what is referred to in the Office Action as combinations "known to the art as admitted by applicant." From this it is presumed that the Examiner is referring to information cited by the Applicant as evidence that the Applicant used to teach the effects of a combination of aspirin and

vitamins in the specification and further, the evidence that the Applicant used to establish the recommended dosages of aspirin and vitamins in the present invention. In response, the Applicant again respectfully argues that there is a difference between the members of the general public coincidentally taking aspirin and vitamins simultaneously and a method of treatment for a certain ailment that is prescribed in combination by a physician. As stated by the Federal Court in *In re Bisley*, 197 F.2d 355, (C.C.P.A. 1952) "Though the problem, once realized, may be solved by use of old and known elements, this does not necessarily negate patentability."

To begin, Applicant argues that the present invention is a method of treatment. The specification describing this method of treatment includes examples stating uses of both aspirin and vitamins, which are taken independently of each other and consumed by the public for a variety of reasons. The examples of aspirin and vitamin use are used for support in the specification to demonstrate an established recommended dosage. The determination of patentability cannot be measured by hindsight reconstruction of prior art, as the Examiner is trying to do in the present case. *Machinenfabrik Rieter A.G. v. Greenwood Mills*, 340 F. Supp. 1103 (S.C. 1972). Instead, to establish obviousness the "prior art must provide a motivation or reason for the worker in the art, without the benefit of the appellant's specification," *Ex Parte Chicago Rawhide Manufacturing Co.*, 226 U.S.P.Q. 438 (PTO Bd. App. 1984). The court continues, "The Examiner has not presented any evidence to support the necessary changes in the referenced device to render the here-claimed device unpatentable." The Examiner in the present case similarly has not provided references citing to or suggesting a combination of aspirin and vitamins for any known treatment, let alone the inventive treatment of the patent. The only references cited to by the Examiner are those referred to by the Applicant which were used to establish medical usage and recommended doses for people in various conditions.

The fact that a patent specifically discloses and claims a combination of features previously used in two separate devices is not fatal to patentability. A basic issue is whether applied references, alone or in any combination, suggest the claimed invention as a solution to the specific problem solved. The claimed invention achieved new and unexpected results nowhere suggested in the prior art, and that achievement was overlooked. The district court erroneously focused its inquiry "solely on the product created, rather than on the obviousness or non-obviousness of its creation." The initial inquiry should be directed to the vantage point of attacking the problem solved by the invention at the time the invention was made. Then prior art itself does not suggest or render obvious the claimed solution to that problem, the art involved does not satisfy the criteria of 35 U.S.C. §103 for precluding patentability. *Lindemann maschinefabrik GmbH v. American Hoist and Derrick Co.*, 730 F.2d 1452 (Fed. Cir. 1984).

Similar to Lindemann, the present invention discloses two different pharmaceuticals, presently consumed for health benefits, along with a new method of simultaneous consumption in order to effectively achieve unexpected results for improving a medical condition. The unexpected results were not previously cited in prior art and had an achievement entirely unknown until invented by the Applicant. Not only must hindsight not be used in determining the patentability of an invention but also the present invention should not be analyzed using the knowledge gained since the advent of the invention. Instead the Examiner must view the patentability in light of the knowledge and information held at the time of the invention. Because the prior art does not suggest the claimed method of the invention and because the effects of the present invention were not known at the time of invention, the §103 rejection should be removed by the Examiner.

Finally, the Examiner requested an explanation of how Tables 2 and 3 establish a synergistic effect. The synergistic effect has also been included in the above-referenced affidavit. As stated in the Affidavit by the Applicant, Table 2 is included in the patent application in order to describe the affect of trace minerals in various biological activities within the human body and moreover, the information in Table 2 shows how working together the trace minerals offer more complete action than apart. Further, Table three demonstrates the synergy of the aspirin and multivitamin populations by demonstrating that the people who took a low dose of aspirin had a tendency for better endpoints than

any other combination, and therefore because the benefit of the combination was observed to be more than additive the effect demonstrates synergism.

The application has been amended to correct minor informalities, to further distinguish the application over the prior art, and to more particularly point out and distinctly claim the subject matter which Applicant regards as the invention so as to place the application, as a whole, into a prima facie condition for allowance. Great care has been taken to avoid the introduction of new subject matter into the application as a result of the foregoing modifications.

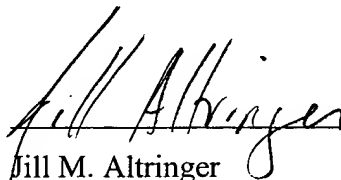
Accordingly, the purpose of the claimed invention is not taught nor suggested by the cited references, nor is there any suggestion or teaching which would lead one skilled in the relevant art to combine the references in a manner which would meet the purpose of the claimed invention. Because the cited references, whether considered alone, or in combination with one another, do not teach nor suggest the purpose of the claimed invention, Applicant respectfully submits that the claimed invention, as amended, patentably distinguishes over the prior art, including the art cited merely of record.

Based on the foregoing, Applicant respectfully submits that its claims are in condition for allowance at this time, patentably distinguishing over the cited prior art. Accordingly, reconsideration of the application and passage to allowance are respectfully solicited.

The Examiner is respectfully urged to call the undersigned attorney at (515) 288-2500 to discuss the claims in an effort to reach a mutual agreement with respect to claim limitations in the present application which will be effective to define the patentable subject matter if the present claims are not deemed to be adequate for this purpose.

Respectfully submitted,

Date: 1-22-2003


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ATTORNEYS FOR APPLICANT



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re Application of)

Group Art Unit: 1614

Kreamer)

Serial No. 08/071,052)

Examiner: Criares

Filed: June 4, 1993)

For: Aspirin and Vitamin and/or Trace)

Element Compositions for the Amelioration)
and Treatment of Vascular Disease)

Assistant Commissioner for Patents
Box Non-Fee Amendment
Washington, D.C. 20231

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
AFFIDAVIT UNDER 37 CFR SECTION 1.131(a)

Dear Sir:

I, Dr. Jeffry Kreamer, the applicant in the above-identified patent application, declare as follows:

1. The original application having the Serial No. 07/317,422 was filed March 1, 1989 and the present application, having the Serial No. 08/071,052 was filed June 4, 1993.
2. The University of Southern California conducted an observational study that was first published November 18, 1989 and addressed only aspirin use of residents within the retirement community. I reviewed the study and then called the researchers at the University of Southern California who had compiled the data they had collected and asked them to analyze the activity of an aspirin and vitamin combination and to send the data to me for use in supporting the present patent application.
3. The compiled data from the University of Southern California had been incidentally collected during the study and the effect of the combination of the aspirin and one or more vitamins had not been appreciated until I requested the additional analysis be coordinated.

4. The study from the University of Southern California, originally published as only addressing aspirin use, was published more than eight months after the filing date of the original application.

5. The study conducted by the University of Southern California did not address the aspirin and vitamin combination until I suggested it and after the filing of the original patent application.

6. The results from the University of Southern California regarding the aspirin and vitamin combination were not published.

7. The data, although collected for the original published study, was not analyzed or appreciated before I suggested the analysis. Following the suggested compilation the results were given to me for my review and use.

8. My suggested compilation and analysis occurred after the filing of my original patent application and was done to further substantiate my patent application.

9. The data collected and results given to me were taken from data collected through 1992, more than three years after my original filing date.

10. I am the inventor of the invention of the above-identified patent application.

11. I was the first to conceptualize the invention and the first to suggest the compilation of data and analysis of the results for the use of an aspirin vitamin combination.

12. Table two describes the thinking of the time as to how these minerals affected various scenarios and thus how working together they could offer a more complete action than apart.

13. Table three demonstrates the synergy of the aspirin and multivitamin populations by showing that the people who took a low dose of aspirin had a tendency for better endpoints than any other category and because much of the time the benefit was more than additive the effect was demonstrated to be synergistic.

The declarant further states that the above statements are made with the knowledge that willful false statements and the like are punishable by fine and/or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that any such willful false statement may jeopardize the validity of this application or any patent resulting therefrom.

Date: 1/22/03


Dr. Jeffry W. Kreamer
Inventor